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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,675	03/07/2001	Rebecca E. Cahoon	BB-1240	3886

7590 08/12/2003

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EXAMINER
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NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/786,675**

Applicant(s)  
**Cahoon et al.**

Examiner  
**Nashaat T. Nashed**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 9, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-48 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

The application has been amended as requested in the communication filed June 9, 2003. Accordingly, claims 15, 21, and 22 have been canceled, and claims 32, 39, 41, 44, and 48 have been amended.

Claims 32-48 are pending and under consideration.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-48 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth in the prior Office action, paper number 17.

In response to the above rejections, Applicants argue that: (a) the instant application teaches an  $\alpha$ - and  $\beta$ -subunit from corn; (b) the  $\beta$ -subunit is not expected to be part of a large family and cite a contradicting evidence supporting the presence of more than one  $\beta$ -subunit in plants; and (c) the  $\beta$ -subunit of farnesyltransferase has a well recognized utility.

Applicants' arguments filed 6/11/03 have been fully considered but they are not deemed to be persuasive. First, the examiner has acknowledged the teaching of a presumed  $\alpha$ -subunit of farnesyltransferase in the previous Office action, paper number 17. There are two main issues in this rejection which the specification have not addresses. They are (a) whether the specific  $\alpha$ - and  $\beta$ -subunits taught in the instant application are capable of form a functional heterodimer or not; and (b) a specific chemical reaction which said heterodimer catalyzes. On page 5 of the applicant response, Applicants write "FTase [farnesyltransferase] and GGTase-I [geranygeranyltransferase] are heterodimeric enzymes with common alpha subunit but distinct beta subunits that determine substrate specificity", under lining added for emphases. Applicants logic appears to be, since a few FTase are known in the prior art and that an  $\alpha$ -subunit may form a functional heterodimeric enzyme with more than one  $\beta$ -subunit, they have taught nucleic acid encoding a functional heterodimer enzyme. The fact that there are limited number of species from a genus known in the prior art does not make an observation based on this limited number species true. The main issue in this rejection is specific or substantial utility. At least, we know the facts that there are more than a single reaction catalyzed by farnesyltransferase, and the  $\beta$ -subunit determine the substrate specificity for the heterodimer. The specification fails to teach any chemical reaction catalyzed by a any heterodimer comprises the specific  $\beta$ -subunit of SEQ ID NO: 12, i. e., no specific chemical utility. Since the protein of SEQ ID NO: 12 appears to be novel, it is not possible to have an established utility. While Pei et

a/. teach the disabling mutation of the coding sequence of a specific  $\beta$ -subunit is accompanied by resistance to drought as indicated by the applicant, they also teach:

"Protein farnesylation plays important and diverse roles in cellular processes and signal transduction cascades which control cell growth, division, morphology, and visual signaling in eukaryotic cells. .... In plants, roles for protein farnesylation have been demonstrated in cell cycle regulation, and seed germination", see page 289, middle column, of Pei *et al.* (Science 1998, 282, 287-290).

Thus, it appears that there are many farnesyltransferases in plants, at least the  $\beta$ -subunits, having different function which are required for regulating plant cell cycle and seed germination. Applicants should note the well known fact that sequence homology alone does not impart functional homology, and it is not possible to determine a substrate specificity and utility from a sequence homology. Thus, the claims remain rejected for lack of utility.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-48 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the reasons set forth in the prior Office action, paper number 17.

Claims 32-48 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement for the reasons set forth in the prior Office action, paper number 17.

In response to the above rejections, Applicants argue knowledge about conserved domains and active site residues, present in sequences from the art and specification, provide specific guidance to one of ordinary skill as to which structures are likely to have enzymatic activity.

Applicants' arguments filed 6/11/03 have been fully considered but they are not deemed to be persuasive. As indicated above, protein FT's are a diverse group of enzymes involved in diverse biological functions. The specification fails to provide an enzymatically active form of the enzyme, and has not identified a substrate for this particular FT  $\beta$ -subunit.

Since routine experimentation does include screening for many species of the claimed  $\beta$ -subunit which have a diverse biological and chemical function, one of ordinary skill in the art would need additional guidance such as the  $\alpha$ -subunit to which the  $\beta$ -subunit is able to form a functional heterodimer, the substrate for the heterodimer, and the biological role for said  $\beta$ -subunit and its companion  $\alpha$ -subunit. Thus, the claims remain rejected.

**New Rejection:**

Claims 32-34, 37-46 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 32-34, 37-46 and 48 are directed to DNAs encoding a  $\beta$ -subunit of FT having 80-95% sequence homology to the amino acid sequence of SEQ ID NO: 2, polypeptides encoded by the nucleic acid, vector and host cell cells comprising said nucleic acid, and method of using the nucleic acid. The specification, however, only provides a single representative species from corn encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. It fails to provide an assay method for the catalytic activity of the  $\beta$ -subunit, identify the specific  $\alpha$ -subunit to which said  $\beta$ -unit is able to bind and form a functional enzyme, or identify a specific substrate for said heterodimer. The specification also fails to describe additional representative species of these DNAs by any identifying structural characteristics or properties other than the properties recited in claim 32, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

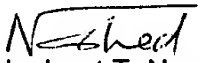
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner